

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

UNITED STATES OF AMERICA,
ex rel. PETER HUESEMAN

Plaintiff,

v.

PROFESSIONAL COMPOUNDING CENTERS
OF AMERICA, INC.,

Defendant.

No. SA-14-CA-00212-XR

**THE UNITED STATES' RESPONSE TO DEFENDANT'S
NOTICE OF SUPPLEMENTAL AUTHORITY**

In *United States ex rel. Cairns v. D.S. Med. LLC*, 42 F.4th 828, 831 (8th Cir. 2022), the Eighth Circuit interpreted the “resulting from” language in 42 U.S.C §1320a-7b(g) of the Anti-Kickback Statute to require but-for causation “when a plaintiff seeks to establish falsity or fraud through” that provision. *Cairns*, 42 F.4th at 836. PCCA now argues that *Cairns* requires dismissal of the government’s entire complaint in intervention.¹

This Court should reject PCCA’s argument for three main reasons. First, *Cairns*’ interpretation of Section 1320a-7b(g) is inconsistent with other circuit precedent and has been rejected by numerous courts outside the Eighth Circuit. Second, the detailed allegations in the government’s complaint in this case satisfy the applicable pleading standard for causation and the even more demanding causal nexus articulated in *Cairns*. Third, the government has not relied “exclusively” on Section 1320a-7b(g) to demonstrate falsity but has asserted alternative theories

¹ In its motion to dismiss, PCCA failed to argue that 42 U.S.C §1320a-7b(g) requires but-for-causation or even cite Section 1320a-7b(g) in its opening and reply brief. In fact, PCCA stated that “Causation under the FCA requires proximate cause, not merely ‘but for’ cause.” Dkt. 84, at 46 (quotations omitted). PCCA should not be allowed to raise new arguments more than five months after briefing closed and oral argument was held. See *Espinoza v. Pompeo*, No. SA-19-CV-01363-XR, 2020 WL 1941300, at *5 (W.D. Tex. Apr. 22, 2020) (noting that “the Court typically does not consider arguments raised for the first time in a reply brief”) (Rodriguez, J.).

of falsity under the False Claims Act and other claims for recovery under federal common law. *Cairns* does not apply to these alternative theories of falsity or to the common law claims. This Court should deny PCCA's motion to dismiss in its entirety as explained more fully in the government's prior briefing and at oral argument.

The AKS states in relevant part that "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of" the FCA. 42 U.S.C. § 1320a-7b(g). In *Cairns*, the Eighth Circuit held that this provision's "resulting from" language "creates a but-for causal requirement between an anti-kickback violation and the 'items or services' included in the claim." *Cairns*, 42 F.4th at 831. The Court emphasized that "[o]ur ruling today is narrow" and "[w]e do not suggest that every case arising under the False Claims Act requires a showing of but-for causation." *Id.* at 836. Because the "government's sole theory at trial hinged" on Section 1320a-7b(g) and "the district court never instructed the jury on but-for causation," the Eighth Circuit reversed and remanded for a new trial. *Id.* at 837.

As an initial matter, the majority of courts having considered the meaning of the "resulting from" language in 42 U.S.C. § 1320a-7b(g) have correctly rejected a but-for causation standard. Indeed, *Cairns* itself recognized (42 F.4th at 836) that its ruling conflicted with *United States ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89 (3d Cir. 2018). In *Greenfield*, the Third Circuit considered "what 'link' is sufficient to connect an alleged kickback scheme to a subsequent claim for reimbursement: a direct causal link, no link at all, or something in between." *Id.* at 95. Rejecting the but-for standard, the Third Circuit held, "For a False Claims Act violation, [the plaintiff] must prove that at least one of [the] claims sought reimbursement for medical care that was provided in violation of the Anti-Kickback Statute (as a kickback renders a subsequent claim ineligible for payment)." *Id.* at 98.

Other courts that have dealt with this issue since *Cairns* have not adopted a but-for causation requirement. See *United States ex rel. Fitzer v. Allergan, Inc.*, 2022 WL 3599139, at *10 (D. Md. Aug. 23, 2022) (“[t]his Court declines to adopt the but-for cause standard endorsed by *Cairns*”); *United States ex rel. Everest Principals, LLC v. Abbott Labs., Inc.*, 2022 WL 3567063, at *8 (S.D. Cal. Aug. 18, 2022) (acknowledging the split of authority, but requiring only a “‘link’ at this stage of the proceedings”); *U.S. ex rel. Siegel v. Novo Nordisk, Inc.*, 2022 WL 16716299, at *5 (W.D. Ok. Nov. 4, 2022) (“[s]o long as Plaintiffs ‘plead with particularity that [Novo Nordisk] made kickbacks with the intent of including referrals and plead ‘particular details of a scheme . . . paired with reliable indicia that lead to a stronger inference that claims were actually submitted,’ the separate elements of the AKS and FCA are satisfied.”).

Numerous courts have reached the same conclusion prior to *Cairns*. See, e.g., *Kuzma v. Northern Ariz. Healthcare Corp.*, 2022 WL 2159027, at *10 (D. Ariz. June 15, 2022) (noting that the “key conclusions” of *Greenfield* have been followed by most courts and “but-for causation is not required.”); *United States v. Medtronic, Inc.*, 2021 WL 4168140, at *23 (D. Kan. Sept. 14, 2021) (noting that Section 1320a-7b(g) “does not expressly summon a but-for causation standard”); see also *United States v. Teva Pharm. USA, Inc.*, 2019 WL 1245656, at *23 (S.D.N.Y. Feb. 27, 2019); *United States ex rel. Bawduniak v. Biogen Idec, Inc.*, 2018 WL 1996829, at *6 (D. Mass. Apr. 27, 2018); *United States ex rel. Kester v. Novartis Pharm. Corp.*, 41 F. Supp. 3d 323, 331-335 (S.D.N.Y. 2014). Interpreting Section 1320a-7b(g) and citing *Greenfield*, this Court has held, “[I]f claims are submitted in violation of the AKS, they are considered false claims under the FCA as a matter of law.” *United States ex rel. Wheeler v. Union Treatment Centers, LLC*, No. CV SA-13-CA-4-XR, 2019 WL 571349, at *5 & n.5 (W.D. Tex. Feb. 12, 2019) (Rodriguez, J.).

This standard is consistent with the AKS, which was designed to prevent improper financial consideration that *might* influence medical judgments. Proving a violation of the AKS does not require that a kickback be successful or proof that the services would not have otherwise been provided in order for the kickback to be illegal: If the remuneration aimed at an item or service violates the AKS (because it was solicited or received “in return for,” or offered or paid “to induce,” referrals for the provision of items of services, 42 U.S.C. § 1320a-7b(b)(1)-(2)) and a claim is submitted to a federal health care program for that item or service, the claim is false and it is error to engage in or require a further inquiry into the practical likelihood that the item or service would have been provided even without the kickback. *See U.S. ex rel. Parikh v. Citizens Med. Ctr.*, 977 F. Supp. 2d 654, 665 (S.D. Tex. 2013) (quoting *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009)), *aff’d sub nom. U.S. ex rel. Parikh v. Brown*, 587 F. App’x 123 (5th Cir. 2014).

While the Fifth Circuit has not directly addressed this issue, this Court need not, and therefore should not, resolve which standard applies because the government’s allegations are more than sufficient at the pleading stage. *See Everest Principals*, 2022 WL 3567063, at *8 (declining to resolve dispute over Section 1320a-7b(g)’s causation requirement where allegations sufficient at pleading stage). As long as the government “plead[ed] with particularity that [PCCA] made kickbacks with the intent of inducing referrals, and [the government] plead[ed] ‘particular details of a scheme . . . paired with reliable indicia that lead to a strong inference that claims were actually submitted,’ the separate elements of the AKS and FCA are satisfied.” *Parikh*, 977 F.Supp.2d 654, 665 (quoting *Grubbs*, 565 F.3d at 190). The government did that and more.

The complaint, taken as true, alleges that PCCA knowingly and willfully offered remuneration to its customers through inflated AWP, large profit spreads, and other benefits (like

vacations) to induce the sale of its ingredients reimbursed by TRICARE. Dkt. 66 at ¶¶52–111, 141–49. It further alleges that PCCA assisted its customers in maximizing profitability from its inflated AWP through training, billing software, consulting services, and educational seminars on third-party billing and strategies. *Id.* at ¶¶112–17. PCCA’s actions led to a rapid increase in the submission of compound prescription claims containing PCCA ingredients with inflated AWP to the TRICARE program. *Id.* at ¶¶133–34, 139–40. The government identified 325 claims submitted by PCCA customers with PCCA ingredients with inflated AWP paid by TRICARE. *Id.* at Ex. 22. And PCCA’s “Diamond” customers—who were offered or attended vacations to induce the purchase of PCCA ingredients—also submitted claims to TRICARE for reimbursement for PCCA ingredients. *Id.* at ¶¶142, 163.

Because the government’s complaint more than satisfies *Grubbs*, that ends the inquiry. But the complaint further satisfies the standard under *Greenfield* because the government’s allegations link PCCA’s AKS violations to the false claims submitted to TRICARE—PCCA inflated its AWP, marketed the spread, and provided other benefits to induce the purchase of PCCA ingredients by customers who submitted claims to TRICARE for reimbursement for those ingredients. *See Fitzer*, 2022 WL 3599139, at *11 (“These allegations link the alleged AKS violation to the allegedly false claims because they demonstrate that at least two surgeons . . . submitted claims for reimbursement for LAP-BAND surgeries performed during the same years in which they were listed on the locator [i.e., the unlawful renumeration].”).

The allegations satisfy the standard under *Cairns* as well. PCCA contended that its customers would have stopped purchasing its ingredients had PCCA not offered the unlawful renumeration. *See* Dkt. 66 at ¶¶ 69-71 (PCCA’s president explaining that inflated AWP were necessary to maintain market share). Indeed, PCCA emphasizes the point in its briefing.

See Dkt. 84 at 19, 55 (“PCCA was faced with a choice of losing all of its customers and going out of business or following the lead of the market.”). In other words, the government has sufficiently alleged that, but for PCCA’s unlawful remuneration, its customers would neither have purchased those ingredients, nor submitted claims containing those ingredients to TRICARE at inflated amounts.²

Finally, contrary to PCCA’s argument, the *Cairns* Court itself acknowledged that not “every case arising under the False Claims Act requires a showing of but-for causation.” 42 F.4th at 836. Unlike *Cairns*, in which the government relied “solely” on Section 1320a-7b(g) to demonstrate falsity, the government here pleaded multiple alternate theories of falsity under the FCA, and common law claims independent of Section 1320a-7b(g). See Dkt. 66 ¶¶180-201; see also Dkt. 91 at 32-47, 54-61. Specifically, the government alleged that PCCA reported false and fraudulent AWP’s that were material to TRICARE’s payment for compound claims; that PCCA engaged in a fraudulent course of conduct that caused TRICARE to pay excessive reimbursement for compound claims containing PCCA ingredients; and, that PCCA’s fraudulent conduct caused its customers to submit TRICARE claims that falsely certified compliance with the AKS, TRICARE regulations, and ESI’s provider agreements. See Dkt. 91 at 30-32.³ *Cairns* has no impact on these claims because *Cairns*’ but-for causation requirement applies only “when a plaintiff seeks to establish falsity or fraud through” Section 1320a-7b(g) of the Anti-Kickback Statute. *Cairns*, 42 F.4th at 836.

² Because the allegations are sufficient under *Grubbs* and PCCA’s arguments have arisen in the context of its Notice of Supplemental Authority, it is premature for the government to set forth all its arguments as to the proper causal standard under Section 1320a-7b(g). The government reserves the right to address this issue more fully at the appropriate time.

³ A claim can be false where it falsely certifies compliance—either expressly or implicitly—with a material statutory, regulatory, or contractual requirement. *Universal Health Servs., Inc. v. United States*, 579 U.S. 176, 187-190 (2016). This is separate and apart from falsity under Section 1320a-7b(g).

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that, on November 22, 2022, I served the foregoing document via CM/ECF on all counsel of record registered to receive CM/ECF notifications.

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